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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Brand *et al.*  
SERIAL NUMBER: 10/532,295 EXAMINER: Elly Gerald Stoica  
FILING DATE: February 17, 2006 ART UNIT: 1647  
FOR: TREATMENT OF DIABETES

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Transmitted herewith for filing in the present application are the following documents:

1. Supplemental Information Disclosure Statement (1 page), in duplicate;
2. Modified Form 1449/PTO (8 pages), in duplicate;
3. Copies of Cited References: B5-B19; C15-C130;
4. Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 24492-011 NATL. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529  
David E. Johnson, Reg. No. 41,874  
Attorney(s) for Applicants  
MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.

Address all written correspondence to

**Customer No.: 30623**

Tel: (617) 542-6000

Fax: (617) 542-2241

Dated: March 7, 2007



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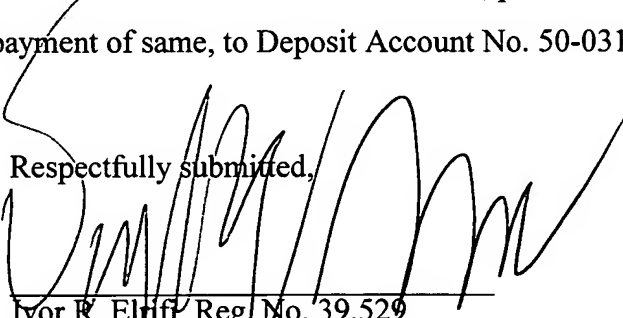
Mail Stop Amendment  
Commissioner for Patents  
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action based on the merits in the above-identified case. Accordingly, no fee or certification is believed due. By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A12-A23 and U.S. Published Applications A24-A37 are not submitted. However, please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 24492-011 NATL.

Respectfully submitted,

  
Ivor R. Eliff, Reg. No. 39,529  
David E. Johnson, Reg. No. 41,874  
Attorney(s) for Applicants  
MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.  
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Modified Form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number		10/532,295	
				Filing Date		February 17, 2006	
				First Named Inventor		Brand	
				Group Art Unit		1647	
				Examiner Name		Elly Gerald Stoica	
				Attorney Docket Number		24492-011 NATL	
<b>U.S. PATENT DOCUMENTS</b>							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A12	3,487,139	12/30/69	Mojonnier et al.	264	132	
	*A13	4,289,817	09/15/81	Valyi	428	35	
	*A14	4,421,712	12/20/83	Winstead	264	551	
	*A15	5,766,525	06/16/98	Andersen et al.	264	40.1	
	*A16	5,885,956	03/23/99	Nardi et al.	514	2	
	*A17	6,288,301 B1	09/11/01	Nardi et al.	800	18	
	*A18	6,358,924 B1	03/19/02	Hoffmann	514	12	
	*A19	6,558,952 B1	05/06/03	Parikh et al.	435	384	
	*A20	6,899,883 B2	05/31/05	Dupre	424	198.1	
	*A21	6,989,148 B2	01/24/06	Dupre	424	198.1	
	*A22	6,992,060 B2	01/31/06	Brand	514	2	
	*A23	7,037,504 B2	05/02/06	Magil et al.	424	198.1	
<b>U.S. PUBLISHED APPLICATION DOCUMENTS</b>							
Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A24	2002/0081285	06/27/02	Parikh et al.	424	93.21	
	*A25	2002/0119146 A1	08/29/02	Dupre	424	139.1	
	*A26	2002/0182728 A1	12/05/02	Ramiya et al.	435	366	
	*A27	2003/0032183 A1	02/13/03	Sheridan	435	370	
	*A28	2004/0023885 A1	02/05/04	Brand et al.	514	12	
	*A29	2004/0037818 A1	02/26/04	Brand et al.	424	93.21	
	*A30	2004/0209801 A1	10/21/04	Brand et al.	514	12	
	*A31	2004/0209816 A1	10/21/04	Parikh et al.	514	12	
	*A32	2004/0229810 A1	11/18/04	Cruz	514	14	
	*A33	2004/0266682 A1	12/30/04	Cruz	514	12	
	*A34	2006/0183674 A1	08/17/06	Brand et al.	514	11	
	*A35	2006/0189520 A1	08/24/06	Brand et al.	514	12	

	*A36	2006/0234373 A1	10/19/06	Rabinovitch et al.	435	325	
	*A37	2006/0234932 A1	10/19/06	Brand	514	12	
FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)		Date of Publication	Translation Yes No	
	B5	EP	0 507 555 A1	AMERICAN HOME PRODUCTS CORPORATION	10/07/92		
	B6	CA	2 494 134	WARATAH PHARMACEUTICALS, INC.	12/04/03		
	B7	CA	2 486 584	WARATAH PHARMACEUTICALS, INC.	12/18/03		
	B8	WO	95/19785	RESEARCH TRIANGLE PHARMACEUTICALS LTD.	07/27/95		
	B9	WO	00/044400	RTP PHARMA INC.; THE GENERAL HOSPITAL CORPORATION	08/03/00		
	B10	WO	02/055152 A2	WARATAH PHARMACEUTICALS, INC.	07/18/02		
	B11	WO	03/040310 A2	WARATAH PHARMACEUTICALS, INC.	05/15/03		
	B12	WO	03/100024 A2	WARATAH PHARMACEUTICALS, INC.; UNIVERSITY OF ALBERTA	12/04/03		
	B13	WO	03/103701 A1	WARATAH PHARMACEUTICALS, INC.	12/18/03		
	B14	WO	2004/037195 A2	WARATAH PHARMACEUTICALS, INC.	05/06/04		
	B15	WO	2004/045640 A1	WARATAH PHARMACEUTICALS, INC.	06/03/04		
	B16	WO	2004/096853 A1	WARATAH PHARMACEUTICALS, INC.	11/11/04		
	B17	WO	2004/105780 A2	WARATAH PHARMACEUTICALS, INC.	12/09/04		
	B18	WO	2005/072045 A2	WARATAH PHARMACEUTICALS, INC.	08/11/05		
	B19	WO	2006/002532 A1	WARATAH PHARMACEUTICALS, INC.	01/12/06		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C15	Adams et al., "Insulin-like growth factor-I promotes successful fetal pancreas transplantation in the intramuscular site", <i>Surgery</i> , 116:751-757 (1994)
	C16	Andrews et al., "Isolation and structures of Glucagon and Glucagon-like peptide from catfish pancreas", <i>J. Biol. Chem.</i> , 260:3910-3914 (1985)
	C17	Baggio et al., "Sustained expression of exendin-4 does not perturb glucose homeostasis, $\beta$ -cell mass, or food intake in metallothionein-preproexendin transgenic mice", <i>J. Biol. Chem.</i> , 275:34472-34477 (2000)
	C18	Berendsen, "A glimpse of the holy grail?", <i>Science</i> , 282:642-643 (1998)
	C19	Brelje et al., "The physiological roles of prolactin, growth hormone and placental lactogen in the regulation of islet $\beta$ cell proliferation", <i>Pancreatic Growth and Regeneration</i> , Ed. N. Sarvetnick, Ch. 1, pgs. 1-30 (1997)
	C20	Carpenter et al., in <i>Peptide Growth Factors</i> , Chapter 4, "The Epidermal Growth Factor Family", eds. Sporn and Roberts, Springer Verlag, pgs. 69-171 (1990)
	C21	Chedid et al., "Regulation of Keratinocyte Growth Factor Gene Expression by Interleukin 1", <i>J Biol. Chem.</i> , 269(14):10753-10757 (1994)
	C22	Cunningham et al., "Receptor and antibody Epitopes in human growth hormone identified by homolog-scanning mutagenesis", <i>Science</i> , 243:1330-1336 (1989)
	C23	Cunningham, et al., "High-resolution epitope mapping of hGH-receptor interactions by alanine-scanning mutagenesis", <i>Science</i> , 244:1081-1085 (1989)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C24	D'Alessio, et al., "Glucagon-like Peptide 1 Enhances Glucose Tolerance Both by Stimulation of Insulin Release and by Increasing Insulin-independent Glucose Disposal", <i>J. Clin. Invest.</i> , 93:2263-2266 (1994)
	C25	Dockray et al., "Immunochemical Characterization of Gastrin in Pancreatic Islets of Normal and Genetically Obese Mice", <i>J. Endocrinol.</i> , 72: pp 143-151 (1977)
	C26	Dupre, et al., "Insulinotropic Effect of Glucagon-Like Peptide I (7-36) Amide in C-Peptide-Positive Type I Diabetes Mellitus," <b>Abstract 221</b> , Page B38, <i>Clin. Invest. Med.</i> (1994)
	C27	Durrant et al., "Co-stimulation of Gastrointestinal Tumour Cell Growth by Gastrin, Transforming Growth Factor $\alpha$ and Insulin Like Growth Factor-1", <i>Br. J. Cancer</i> , 63:67-70 (1991)
	C28	Edwards et al., "Exendin-4 Reduces Fasting and Postprandial Glucose and Decreases Energy Intake in Healthy Volunteers", <i>Am. J. Physiol. Endocrinol. Metab.</i> 281:E155-E161 (2001)
	C29	Egan et al., "Glucagon-like Peptide-1 (7-36) Amide (GLP-1) Enhances Insulin-Stimulated Glucose Metabolism in 3T3-L1 Adipocytes: One of Several Potential Extrapancreatic Sites of GLP-1 Action", <i>Endocrinol.</i> , 135(5):2070-2075 (1994)
	C30	Fehmann et al., "Insulinotropic Hormone Glucagon-like Peptide-1(7-37) Stimulation of Proinsulin Gene Expression and Proinsulin Biosynthesis in Insulinoma Beta TC-1 Cells", <i>Endocrinol.</i> , 130(1):159-66 (1992)
	C31	Ghiglionone et al., "How Glucagon-Like is Glucagon-Like peptide?", <i>Diabetologia</i> , 27:599-600 (1984)
	C32	Gil et al., "Polymeric Biomaterials as drug delivery systems", <i>Boletim de Biotecnologia</i> , 72:13-19 (2002)
	C33	Goeddel et al., "Direct expression in Escherichia coli of a DNA sequence coding for human growth hormone", <i>Nature</i> , 281:544-548 (1979)
	C34	Goke et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-Amide an Antagonist at the Glucagon-Like Peptide 1-(7-36)-Amide Receptor of Insulin-Secreting Beta-Cells", <i>J. Biol. Chem.</i> , 268:19650-19655 (1993)
	C35	Gray et al., "Periplasmic production of correctly processed human growth hormone in Escherichia coli: natural and bacterial signal sequences are interchangeable", <i>Gene</i> , 39:247-254 (1985)
	C36	Gromada et al., "Cellular Regulation of Islet Hormone Secretion by the Incretin Hormone Glucagon-like Peptide 1", <i>Eur. J. Physiol.</i> , 435:583-94 (1998)
	C37	Gromada et al., "Desensitization of Glucagon-like Peptide 1 Receptors in Insulin-secreting .beta.TC3 Cells: Role of PKA-independent Mechanisms ", <i>Brit. J. Pharmacol.</i> , 118:769-775 (1996)
	C38	Gromada et al., "Glucagon-Like Peptide 1(7-36) Amide Stimulates Exocytosis in Human Pancreatic .beta.-Cells by Both Proximal and Distal Regulatory Steps in Stimulus-Secretion Coupling", <i>Diabetes</i> , 47:57-65 (1998)
	C39	Gutniak et al., "Glucagon-Like Insulinotropic Peptide 1 (7-36)--New Approach to Treating Diabetes?," <i>Diabetologia</i> , (Published from the 26.sup.th Annual Meeting of the European Association for the Study of Diabetes), <b>Abstract 246</b> , 33(Supp.):A73 (1990)
	C40	Gutniak et al., "Antidiabetogenic Effect of Glucagon-Like Peptide-1 (7-36) Amide in Normal Subjects and Patients with Diabetes Mellitus", <i>N. Eng. J. Med.</i> , 326(20):1316-1322 (1992)
	C41	Hargrove et al., "Comparison of the Glucose Dependency of Glucagon-Like Peptide-1(7-37) and Glyburide In Vitro and In Vivo", <i>Metabolism</i> , 45(3):404-409 (1996)
	C42	Hargrove et al., "Glucose-Dependent Action of Glucagon-Like Peptide-1(7-37) In Vivo During Short- or Long-Term Administration," <i>Metabolism</i> , 44(9):1231-1237 (1995)
	C43	Hendrick et al., "Glucagon-like Peptide 1 (7-37) Blunts Postprandial Glycaemic Excursion in Rats with Mild Diabetes," <i>Diabetologia</i> , <b>Abstract 212</b> , 32(7):496A (1989)

C44	Hendrick et al., "Glucagon-like Peptide-I-(7-37) Suppress Hyperglycemia in Rats", <i>Metabolism</i> , 42(1):1-6 (1993)
C45	Hollande et al., "In Vitro Secretion of Gastrin, Insulin, and Glucagon in Tissue Cultures of Pancreas From a Child with Neonatal Intractable Hypoglycemia", <i>Gastroenterology</i> , 71:255-262 (1976)
C46	Holst, J.J., "Glucagon Peptide 1: A Newly Discovered Gastrointestinal Hormone," <i>Gastroenterology</i> , 107(6):1848-1855 (1994)
C47	Holstad et al., "Prolactin Protects Against Diabetes Induced by Multiple Low Doses of Streptozotocin in Mice", <i>J. Endocrinol.</i> , 163:229-234 (1999)
C48	Hui et al., "Glucagon-like peptide 1 induces differentiation of islet duodenalhomeobox-1-positive pancreatic ductal cells into insulin-secreting cells", <i>Diabetes</i> , 50:785-796 (2001)
C49	Hvidberg et al., "Effect of Glucagon-like Peptide-1 (proglucagon78-107amide) on Hepatic Glucose Production in Healthy Man", <i>Metabolism</i> , 43(1):104-108 (1994)
C50	Imura H., "A Novel Antidiabetic Drug, Troglitazone--Reason for Hope and Concern", <i>N. Engl. J. Med.</i> , 338:908-909 (1998)
C51	Iritani et al., "Oral Triacylglycerols Regulate Plasma Glucagon-Like Peptide-1(7-36) and Insulin Levels in Normal and Especially in Obese Rats", <i>J. Nutr.</i> , 129:46-50 (1999)
C52	Johnson et al., "Erythropoietin mimetic peptides and the future", <i>Nephrol. Dial Transpl.</i> , 15:1274-1277 (2000)
C53	Kaushansky, K., "Hematopoietic growth factor mimetics", <i>Ann. NY Acad. Sci.</i> , 938:131-138 (2001)
C54	Knudsen et al., "Potent Derivatives of Glucagon-like Peptide-1 with Pharmacokinetic Properties Suitable for Once Daily Administration", <i>J. Med. Chem.</i> , 43(9):1664-1669 (2000)
C55	Krakowski et al., "Pancreatic Expression of Keratinocyte Growth Factor Leads to Differentiation of Islet Hepatocytes and Proliferation of Duct Cells", <i>Am. J. Pathol.</i> , 154:683-691 (1999)
C56	Krakowski et al., "Transgenic Expression of Epidermal Growth Factor and Keratinocyte Growth Factor in Beta-Cells Results in Substantial Morphological Changes", <i>J. Endocrinol.</i> , 162:167-175 (1999)
C57	Kreymann et al., "Glucagon-like peptide-1 7-36: A physiological incretin in man," <i>Lancet</i> , 2:1300-1304 (1987)
C58	Kreymann et al., "Glucagon-like Peptide-1 7-36 Amide, A New Brain-Gut Hormone and Its Effect of Pancreatic Endocrine Function in Man," <i>Biomed. Res.</i> 9(Supp. 3):207-211 (1988)
C59	Kumar, M., "Nano and microparticles as controlled drug delivery devices", <i>J. Pharm. Pharmaceut. Sci.</i> , 3:234-258 (2002)
C60	Kumar et al., "Biodegradable block copolymers", <i>Adv. Drug Deliv. Rev.</i> , 53:23-44 (2001)
C61	Larsen et al., "Glucagons-Like Peptide-1 Infusion Must Be Maintained For 24 H/Day To Obtain Acceptable Glycemia In Type 2 Diabetic Patients Who Are Poorly Controlled On Sulphonylurea Treatment", <i>Diabetes Care</i> , 24(8):1416-1421 (2001)
C62	Larsen et al., "Systemic Administration of the Long-Acting GLP-1 Derivative NN2211 Induces Lasting and Reversible Weight Loss in Both Normal and Obese Rats", <i>Diabetes</i> , 50:2530-2539 (2001)
C63	Le Bras et al., "Fibroblast Growth Factor 2 Promotes Pancreatic Epithelial Cell Proliferation Via Functional Fibroblast Growth Factor Receptors During Embryonic Life", <i>Diabetes</i> 47:1236-1242 (1998)
C64	Lima-Leite et al., "Synthesis and Biological Activities of the Human Gastrin analogs", <i>Braz. J. Med. Biol. Res.</i> , 29:1253-1263 (1996)
C65	Lingohr et al., "Activation of IRS-2-Mediated Signal Transduction by IGF-1, but Not TGF- Alpha or EGF, Augments Pancreatic Beta-Cell Proliferation", <i>Diabetes</i> , 51:966-976 (2002)
C66	Logothetopoulos et al., in <i>Handbook of Physiology</i> (Am. Physiol. Soc. Washington, DC), Section 7, Chapter 3, pgs. 67-75 (1972)

C67	Lu et al., "Keratinocyte growth factor ameliorates streptozotocin-induced, moderate diabetes in rats", <i>Diabetes</i> , <b>Abstract 1030</b> , 48[s1], A236 (1999)
C68	Marchese et al., "Human Keratinocyte Growth Factor Activity on Proliferation and Differentiation of Human Keratinocytes: Differentiation Response Distinguishes KGF From EGF Family", <i>J. Cell. Physiol.</i> , 144: 326-332 (1990)
C69	Messer, "Vasopressin and Oxytocin", web document updated 04/03/2000, <a href="http://www.neurosci.pharm.utoledo.edu/MBC3320/vasopressin.htm">http://www.neurosci.pharm.utoledo.edu/MBC3320/vasopressin.htm</a> , 5 pages.
C70	Morales et al., Preserved GLP-I Effects on Glycogen Synthase a Activity and Glucose Metabolism in Isolated Hepatocytes and Skeletal Muscle From Diabetic Rats", <i>Diabetes</i> , 46:1264-1269 (1997)
C71	Movassat et al., "Exendin-4 upregulates expression of PDX-1 and hastens differentiation and maturation of human fetal pancreatic $\beta$ cells", <i>Diabetes</i> , <b>Abstract 1416-P</b> , page A341 (2001)
C72	Munoz-Acedo et al., "Pancreatic changes in somatostatin content and receptor/effector system after intrapancreatic injection of 5,7-dihydroxytryptamine", <i>J. Endocrinol.</i> , 145(2):227-234 (1995)
C73	Nakano et al., "Hepatocyte growth factor is essential for amelioration of hyperglycemia in streptozotocin-induced diabetic mice receiving a marginal mass of intrahepatic islet grafts", <i>Transplantation</i> , 69(2):214-221 (2000)
C74	Nathan et al., "Insulinotropic Action of Glucagonlike Peptide-1-(7-37) in Diabetic and Nondiabetic Subjects", <i>Diabetes Care</i> , 15(2):270-276 (1992)
C75	Nauck et al., "Preserved Incretin Activity of Glucagon-like Peptide 1 [7-36 Amide] but Not of Synthetic Human Gastric Inhibitory Polypeptide in Patients with Type-2 Diabetes Mellitus", <i>J. Clin. Invest.</i> , 91:301-307 (1993)
C76	Nauck et al., "Additive Insulinotropic Effects of Exogenous Synthetic Human Gastric Inhibitory Polypeptide and Glucagon-Like Peptide-1-(7-36) Amide Infused at Near-Physiological Insulinotropic Hormone and glucose Concentrations", <i>J. Clin. Endo. and Metab.</i> , 76(4):912-917 (1993)
C77	Nielsen, J.H., "Effects of Growth Hormone, Prolactin, and Placental Lactogen on Insulin Content and Release, and Deoxyribonucleic Acid Synthesis in Cultured Pancreatic Islets", <i>Endocrinology</i> , 110:600-606 (1982)
C78	Nielsen et al., "The Role of Growth Hormone and Prolactin in Beta Cell Growth and Regeneration", <i>Adv. Exp. Med. Biol.</i> , 321:9-17 (1992)
C79	Nielsen et al., "Beta Cell Proliferation and Growth Factors", <i>J. Mol. Med.</i> , 77:62-66 (1999)
C80	Ohlsson et al., "The Method of Administration of Cholecystokinin Determines the Effects Evoked in the Pancreas", <i>Pancreas</i> , 23(1):94-101 (2001)
C81	Ohlsson et al., "The Effect of Intermittent Injections of CCK-8S and the CCK-A Receptor Antagonist Devazepide on Cell Proliferation in Exocrine Rat Pancreas", <i>Int. J. Pancreatol.</i> , 24:211-218 (1998)
C82	Ohlsson et al., "Epidermal growth factor induces cell proliferation in mouse pancreas and salivary glands", <i>Pancreas</i> , 14(1):94-98 (1997)
C83	Orskov et al., "Tissue and plasma concentrations of amidated and glycine-extended glucagon-like peptide I in humans", <i>Diabetes</i> , 43:535-539 (1994)
C84	Parkes et al., "Insulinotropic Actions of Exendin-4 and Glucagon-Like Peptide-1 in Vivo and in Vitro", <i>Metabolism</i> , 50:583-589 (2001)
C85	Pederson et al., "Effect of Cholecystokinin, Secretin, and Gastric Inhibitory Polypeptide on Insulin Release From the Isolated Perfused Rat Pancreas", <i>Can. J. Physiol. Pharmacol.</i> , 57:1233-1237 (1979)
C86	Perfetti et al., "Glucagon-Like Peptide-1 Induces Cell Proliferation and Pancreatic- Duodenum Homeobox-1 Expression and Increases Endocrine Cell Mass in the Pancreas of Old, Glucose-Intolerant Rats", <i>Endocrinology</i> , 141:4600-4605 (2000)

C87	Pierce et al., "Stimulation of All Epithelial Elements During Skin Regeneration by Keratinocyte Growth Factor", <i>J. Exp. Med.</i> , 179:831-840 (1994)
C88	Proietto et al., "Glucose Utilization in Type 1 (Insulin-Dependent) Diabetes: Evidence for a Defect not Reversible by Acute Elevations of Insulin," <i>Diabetologia</i> , 25(4):331-335 (1983)
C89	Rehfeld et al., "The Effect of Gastrin on Basal- and Glucose-Stimulated Insulin Secretion in Man", <i>J. Clin. Invest.</i> , 52:1415-1426 (1973)
C90	Rehfeld, J.F., "The New Biology of Gastrointestinal Hormones", <i>Physiol. Rev.</i> , 78:1087-1108 (1998)
C91	Rehfeld et al., "The Effect of Gastrin and Cholecystokinin on the Endocrine Pancreas", <i>Frontiers of Hormone Research</i> , 7:107-118 (1980)
C92	Ritzel et al., "Glucagon-Like Peptide 1 Increases Secretory Burst Mass of Pulsatile Insulin Secretion in Patients With Type 2 Diabetes and Impaired Glucose Tolerance", <i>Diabetes</i> , 50:776-784 (2001)
C93	Rooman et al., "Effect of Vascular Endothelial Growth Factor on Growth and Differentiation of Pancreatic Ductal Epithelium", <i>Lab. Invest.</i> , 76:225-232 (1997)
C94	Rooman et al., "Mitogenic effect of gastrin and expression of gastrin receptors in duct-like cells of rat pancreas", <i>Gastroenterology</i> , 121:940-949 (2001)
C95	Rooman et al., "Effects of gastrin on proliferating and differentiation in regenerating pancreas", <i>Diabetologia</i> , Abstract, page 106 (2000)
C96	Rooth et al., "Prevention of detrimental effect of cyclosporine A on vascular ingrowth of transplanted pancreatic islets with verapamil", <i>Diabetes</i> , 38(1):202-205 (1989)
C97	Rudinger, J. "Characteristics of the amino acids as components of a peptide hormone sequence" <i>Peptide Hormones</i> , JA Parsons ed., pgs. 1-7 (1976)
C98	Sasaki et al., "Dietary Docosahexaenoic acid can alter the surface expression of CD4 and CD8 on T cells in peripheral blood", <i>J. Agric. Food Chem.</i> , 48(4):1047-1049 (2000)
C99	Schmidt et al., "Glucagon-Like peptide-1 but not Glucagon-like peptide-2 stimulates insulin release from isolated rat pancreatic islets," <i>Diabetologia</i> , 28:704-707 (1985)
C100	Shapiro et al., "Combination Therapy With Low Dose Sirolimus and Tacrolimus Is Synergistic in Preventing Spontaneous and Recurrent Autoimmune Diabetes in Non-Obese Diabetic Mice", <i>Diabetologia</i> , 45:224-230 (2002)
C101	Shapiro et al., "Islet Transplantation in Seven Patients with Type 1 Diabetes Mellitus using a Glucocorticoid-Free Immunosuppressive Regimen", <i>N. Eng. J. Med.</i> , 343(4):230-238 (2000)
C102	Sharma et al., "The homeodomain protein IDX-1 increases after an early burst of proliferation during pancreatic regeneration", <i>Diabetes</i> , 48:507-513 (1999)
C103	SIGMA Big Gastrin 1 human, <a href="https://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/G7264">https://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/G7264</a>
C104	SIGMA Leu15-Gastrin 1 human, <a href="http://www.sigmaaldrich.com/catalog/search/ProductDetail/ProNo=G9145&amp;Brand=Sigma">http://www.sigmaaldrich.com/catalog/search/ProductDetail/ProNo=G9145&amp;Brand=Sigma</a>
C105	<b>SIGMA, Designing Custom Peptides</b> , <a href="http://www.sigma-genosys.com/peptide_design.asp">http://www.sigma-genosys.com/peptide_design.asp</a> (accessed 12/16/2004) 2 pages
C106	Sjoholm et al., "TGF-Beta Stimulates Insulin Secretion and Blocks Mitogenic Response of Pancreatic Beta-Cells to Glucose", <i>Am. J. Physiol.</i> , 260:C1046-C1051 (1991)
C107	Smilek et al., "A single amino acid change in a myelin basic protein peptide confers the capacity to prevent rather than induce experimental autoimmune encephalomyelitis", <i>Proc. Natl. Acad. Sci., USA</i> , 88:9633-9637 (1991)
C108	Soon-Shiong et al., "Glucose-Insulin Kinetics of the Extravascular Bioartificial Pancreas", <i>ASAIO J.</i> , 38:851-854 (1992)
C109	Soon-Shiong et al., "Insulin independence in a type 1 diabetic patient after encapsulated islet transplantation" <i>Lancet</i> , 343:950-951 (1994)



C110	Soon-Shiong et al, "Long-term reversal of diabetes by the injection of immunoprotected islets", <i>Proc. Natl. Acad. Sci. USA</i> , 90(12):5843-5847 (1993)
C111	Soon-Shiong et al, "Pancreas and islet-cell transplantation: Potential cure for diabetes", <i>Transplantation</i> , 87(8):133-134; 139-140 (1990)
C112	Soon-Shiong et al., "Successful reversal of spontaneous diabetes in dogs by Intraperitoneal microencapsulated islets", <i>Transplantation</i> , 54(5):769-774 (1992)
C113	Staiano-Coico et al., "Human Keratinocyte Growth Factor Effects in a Porcine Model of Epidermal Wound Healing", <i>J. Exp. Med.</i> , 178:865-878 (1993)
C114	Todd et al., "Subcutaneous Glucagon-Like Peptide-1 Improves Postprandial Glycaemic Control Over a 3-Week Period in Patients With Early Type 2 Diabetes", <i>Clin. Sci.</i> , 95:325-329 (1998)
C115	Tourrel et al., "Persistent Improvement of Type 2 Diabetes in the Goto-Kakizaki Rat Model by Expansion of the Beta-Cell Mass During the Prediabetic Period With Glucagon-Like Peptide-1 or Exendin-4", <i>Diabetes</i> , 51:1443-1452 (2002)
C116	Tourrel et al., "Glucagon-Like Peptide-1 and Exendin-4 Stimulate Beta-Cell Neogenesis in Streptozotocin-Treated Newborn Rats Resulting in Persistently Improved Glucose Homeostasis at Adult Age", <i>Diabetes</i> , 50:1562-1570 (2001)
C117	Uttenthal et al., "Molecular forms of Glucagon-like peptide-1 in human pancreas and Glucagonomas," <i>J. Clin. Endocrinol. Metab.</i> , 61:472-479 (1985)
C118	Vergelli et al., "Immunosuppressive activity of 13- <i>cis</i> -retinoic acid in rats: aspects of pharmacokinetics and pharmacodynamics", <i>Immunopharmacology</i> , 37:191-197 (1997)
C119	Villanueva-Penacarrillo et al., "Increased Glucagon-like Peptide 1 (7-36) Amide Binding in Adipose Tissue from Non-Insulin Dependent and Insulin-Dependent Diabetic Patients," <i>Diabetes Nutr. Metab.</i> , 7(3):143-148 (1994)
C120	Voet et al., <i>Biochemistry</i> , 2 <sup>nd</sup> Edition, Section 9-3, "Abdominal Hemoglobins", pages 235-241 (1995)
C121	Wang et al., "Intraportal delivery of immunosuppression to intrahepatic islet allograft recipients", <i>Transpl. Int.</i> , 8:268-272 (1995)
C122	Wang et al., "Glucagon-Like Peptide-1 Can Reverse the Age-Related Decline in Glucose Tolerance in Rats", <i>J. Clin. Invest.</i> , 99:2883-2889 (1997)
C123	Wang et al., "Glucagon-Like Peptide-1 Is a Physiological Incretin in Rat", <i>J. Clin. Invest.</i> , 95:417-421 (1995)
C124	Wang et al., "Expression of gastrin and transforming growth factor- $\alpha$ during duct to islet cell differentiation in the pancreas of duct-ligated adult rats", <i>Diabetologia</i> , 40:887-893 (1997)
C125	Wettergren et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man," <i>Digestive Diseases and Sciences</i> , 38(4):665-673 (1993)
C126	Winer et al., "Autoimmune islet destruction in spontaneous type 1 diabetes is not $\beta$ -cell exclusive", <i>Nat. Med.</i> , 9(2):198-205 (2003)
C127	Wrighton et al., "Small peptides as potent mimetics of the protein hormone erythropoietin", <i>Science</i> , 273:458-463 (1996)
C128	Ye et al., "DepoFoam technology: a vehicle for controlled delivery of protein and peptide drugs", <i>J. Controlled Rel.</i> , 64:155-166 (2000)
C129	Young et al., "Glucose-Lowering and Insulin-Sensitizing Actions of Exendin-4: Studies in Obese Diabetic (Ob/Ob, Db/Db) Mice, Diabetic Fatty Zucker Rats, and Diabetic Rhesus Monkeys (Macaca Mulatta)", <i>Diabetes</i> , 48:1026-1034 (1999)

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Attorney Docket No.: 24492-011 NATL

	C130	Zhou et al., "Glucagon-Like Peptide 1 and Exendin-4 Convert Pancreatic AR42J Cells into Glucagon- and Insulin-Producing Cells", <i>Diabetes</i> , 48:2358-2366 (1999)
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**\* By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A12-A23 and the U.S. Published Applications A24-A37 are not submitted.**

Examiner Signature		Date Considered	
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